



**भारत का राजपत्र**  
**The Gazette of India**

### असाधारण

## EXTRAORDINARY

भाग II—खण्ड 2

## PART II — Section 2

प्राधिकार से प्रकाशित

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इस भाग में भिन्न पृष्ठ संख्या दी जाती है जिससे कि यह अलग संकलन के रूप में रखा जा सके।  
Separate paging is given to this Part in order that it may be filed as a separate compilation.

**RAJYA SABHA**

The following Bills were introduced in the Rajya Sabha on 24th November, 2006:—

## I

BILL No. LXIX OF 2006

*A Bill to set up a National Commission to identify and deport illegal immigrants in the country and for matters connected therewith and incidental thereto.*

BE it enacted by Parliament in the Fifty-seventh Year of the Republic of India as follows:—

**1. (1) This Act may be called the Illegal Immigrants (Identification and Deportation) Act, 2006.**

Short title,  
extent and  
commencement.

(2) It extends to the whole of India.

(3) It shall come into force at once.

2. In this Act 'illegal immigrant' means any person who comes to India without any proper and valid document issued by the designated Authority of the Government of India.

**Definition.**

3. The Central Government shall set up a Commission to be known as the National Commission for Identification and Deportation of Illegal Immigrants (hereinafter referred to as the National Commission).

National  
Commission for  
identification  
and deporting  
illegal  
immigrants.

Appointment  
term and  
salary of the  
Chairperson  
and Members  
of the  
Commission.

**4. (1) The National Commission shall consist of,—**

(i) a Chairperson who shall be a retired Judge of the Supreme Court to be appointed by the President; and

(ii) two other members to be appointed by the President.

(2) The Chairperson and other members shall hold office for a term of five years and shall be entitled to such salaries and allowances as may be determined by the Central Government.

State  
Commission.

**5. The Central Government shall also set up a State Commission for a State or two or more States for identification and deportation of illegal immigrants.**

Appointment,  
term and salary  
of Chairperson  
and other  
members  
of State  
Commission.

**6. (1) Every State Commission shall consist of,—**

(i) a Chairperson who shall be a retired Judge of the High Court; and

(ii) four other members.

(2) The Chairperson and other members of the State Commission shall be appointed by the Central Government in consultation with the Chairperson of the National Commission.

(3) The Chairperson and the other members shall hold office for a term of five years and shall be entitled to such salaries and allowances as may be determined by the Central Government.

Functions of  
the State  
Commission.

**7. Every State Commission shall perform the following functions, namely:—**

(i) to carry out necessary exercise to identify illegal immigrants and their nationality in their respective area;

(ii) to prepare and send list of all illegal immigrants in their respective area to the district administration.

Powers of the  
Commissions

**8. The National Commission and every State Commission shall exercise the powers of a civil court in regard to discharge of its functions.**

National  
Commission to  
direct the State  
Government.

**9. The National Commission may direct the respective State Government to:—**

(i) stop all assistance being enjoyed by the illegal immigrants immediately;

(ii) impound the ration card in the possession of illegal immigrants;

(iii) terminate the services of illegal immigrants, in case such immigrants are employed in any public sector and inform persons concerned in case they are employed in private sector;

(iv) take such necessary action to recover loans borrowed by illegal immigrants;

(v) facilitate speedy hearing of cases against illegal immigrants; and

(vi) take immediate action for deporting them to the countries of their origin.

State  
Government to  
take action on  
direction of  
the National  
Commission.

**10. The State Government shall take such action as directed by the National Commission within three months.**

Representation  
to the National  
Commission.

**11. (1) Any person, who has any complaint against a decision of any State Commission, shall be entitled to represent to the National Commission, who shall hear the same and dispose it of within one month.**

(2) Every applicant, who represents to the National Commission under clause (1), shall be given an opportunity of being heard before disposing of such application by the National Commission.

12. The State Commission and the district administration shall ensure that no inconvenience is caused to any *bona fide* citizen of the country during the enforcement of the provisions of this Act. No inconvenience to *bona fide* citizens.

13. The provisions of this Act shall be in addition to and not in derogation of any other law for the time being in force. Savings.

14. The Central Government may, by notification in the Official Gazette, make rules for carrying out the provisions of this Act. Power to make rules.

### STATEMENT OF OBJECTS AND REASONS

In our country, there are lakhs of illegal immigrants who have come from many countries. Our country is poor and cannot afford to feed the immigrants. Moreover, there have been complaints that these people indulge in criminal activities. They take the share of benefits which would have been otherwise available to *bona fide* citizens. They harass the genuine citizens and usurp their rights.

It is, therefore, proposed to set up a National Commission at the National level and State Commissions at State level to identify and deport illegal immigrants to the countries of their origin. Due care has been taken in the proposed legislation not to harass *bona fide* citizens.

Hence this Bill.

MANOHAR JOSHI.

### FINANCIAL MEMORANDUM

Clause 3, of the Bill provides for setting up of the National Commission for identification and deporting of illegal immigrants from the country. Clause 4 provides for salaries and allowances payable to the Chairman and other members of the Commission. Clause 5 provides for setting up of State Commission for a State or a group of States and clause 6 provide for salaries and allowances payable to the Chairman and other members of State Commission.

The Bill, if enacted, will involve expenditure from the Consolidated Fund of India. It is likely to involve a recurring expenditure of about one crore per annum.

A non-recurring expenditure of about rupees ten crore is also likely to be involved.

### MEMORANDUM REGARDING DELEGATED LEGISLATION

Clause 14 of the Bill empowers the Central Government to frame rules for carrying out the purposes of the Bill. Since the rules will relate to matters of detail only, the delegation of legislative power is of a normal character.

## II

## BILL NO. LVI OF 2006

*A Bill further to amend the Constitution of India.*

BE it enacted by Parliament in the Fifty-seventh Year of the Republic of India as follows:—

1. This Act may be called the Constitution (Amendment) Act, 2006. Short title.
2. In article 103 of the Constitution in clause (2) for the words "Election Commission", the words "Electoral Council" shall be substituted. Amendment of article 103.
3. After article 324 of the Constitution the following article shall be inserted, namely:— Insertion of new article 324A.  
  

**"324A. (1) There shall be an Electoral Council consisting of the Chairman of the Council of States, the Speaker of the House of the People, the Chief Election Commissioner, the Chairman, Law Commission and one eminent jurist to be appointed by the President.** Electoral Council.

(2) The Chairman of the Council of States shall be the Chairman of the Electoral Council.

(3) The Electoral Council shall formulate the electoral policy and shall have the power to review decisions taken by the Election Commission in the discharge of its functions."

## STATEMENT OF OBJECTS AND REASONS

The role of Election Commission as seen during earlier elections has become the subject matter of intense debate. The decisions of the Election Commission have been both criticised or acclaimed by the political parties, groups depending upon their political ideologies.

Article 324 of the Constitution vests in the Election Commission the power of superintendence, direction and control of elections which is inherently an administrative power. The Election Commission cannot encompass policy decisions which impinge on the functions of the executive and legislature. Even the judicial intervention had to be sought to resolve certain controversial decisions of the Commission. This has created an unsavoury and anomalous situation.

The time has come to review the provisions of the Part XV of the Constitution. An "Electoral Council" consisting of the Chairman, Rajya Sabha, Speaker, Lok Sabha, Chief Election Commissioner, the Chairman, Law Commission and one eminent jurist should be constituted to review the decisions of the Election Commission. It will enhance transparency and credibility of the role of the Election Commission.

The Bill seeks to achieve the above objectives.

MANOHAR JOSHI

## FINANCIAL MEMORANDUM

Clause 3 of the Bill provides for setting up of Electoral Council consisting of the Chairman of the Council of States, the Speaker of the House of the People, the Chief Election Commissioner, the Chairman, Law Commission and one eminent jurist to be appointed by the President. The Bill, therefore, if enacted, will involve expenditure from the Consolidated Fund of India. It is likely to involve a recurring expenditure of about rupees ten lakh per annum.

It is also likely to involve a non-recurring expenditure of about rupees five lakh.

## III

## BILL NO. XC OF 2006

*A Bill to provide for the welfare of the destitute women and widows and for matters connected therewith.*

BE it enacted by Parliament in the Fifty-seventh Year of the Republic of India as follows:—

1. (1) This Act may be called the Destitute Women and Widows Welfare Act, 2006. Short title,  
extent and  
commencement.
- (2) It extends to the whole of India.
- (3) It shall come into force on such date as the Central Government may, by notification in the Official Gazette, appoint.
2. In this Act, unless the context otherwise requires— Definitions.
  - (a) "Appropriate Government" means in case of a State, the State Government and in other cases, the Central Government;
  - (b) "Authority" means the Destitute Women and Widows Welfare Authority established under section 3;

(c) "Destitute" in relation to a woman and widow means any female who has no independent source of livelihood or is not being looked after by any family member or relative and includes a divorced woman;

(d) "Widow" means a woman whose husband has expired after legal marriage.

Establishment of the Destitute Women and Widows Welfare Authority

3. (1) The Central Government shall by notification in Official Gazette establish an authority, to be known as "the Destitute Women and Widows Welfare Authority" to perform functions assigned under this Act.

(2) The composition of the Authority shall be such as may be prescribed—

Provided that the Authority shall not have less than ten members.

(3) The Central Government shall provide to the Authority such number of officers and employees on such terms and conditions as may be prescribed.

(4) The Authority may establish as many offices in States and UT as may be necessary for its efficient functioning.

Functions of Authority.

4. It shall be the function of the Authority:—

(1) to register names of all destitute women and widows residing in the country, and

(2) to formulate plans and schemes for the welfare of the destitute women and widows.

Authority to provide facilities.

5. The Authority shall provide to every destitute woman or a widow registered under section, 4, the following facilities namely:—

(a) Subsistence allowance not exceeding rupees two thousand per month or such financial assistance as may be determined by the Subsistence Expenditure Index whichever is more;

(b) free medical assistance;

(c) free residential facilities wherever necessary;

(d) free education including technical education to the dependent children of the destitute women and widows;

(e) gainful employment;

(f) vocational training;

(g) free travelling facilities by public transport and also concessions in privately owned transport;

(h) interest free loans for the purpose of housing and self employment; and

(i) such other facilities which are necessary for her proper development and welfare.

Central Government to provide funds.

6. The Central Government shall, from time to time, after due appropriation made by Parliament by law in this behalf, provide adequate fund to the Authority for carrying out the purpose of this Act.

Power to make rules

7. The Central Government may by notification in the Official Gazette make rules for carrying out the purposes of this Act.



## STATEMENT OF OBJECTS AND REASONS

A very large number of destitute women and widows in our country are leading a miserable life. They do not have any means for their own subsistence and for their dependent children. They work as maids and perform various domestic chores such as cleaning utensils, washing cloths, dusting, etc. for very small wages. They can do such a work only when they are physically healthy. But many widows are not so fortunate. Being old, physically weak or having been suffering from serious and chronic diseases they are incapable of doing physical labour. In many cases, they are mentally depressed. Such helpless widows, perforce have to take to begging in streets for their livelihood. Many young widows are forced into prostitution and many of them have to opt it as a profession to avoid starvation. Many widows are forced to leave their families after the death of their husbands and generally they move to other places leaving their family for the sake of peace and relief. In many cases, such widows become victims of sexual exploitation at the hands of unscrupulous persons at such places. In many cases, widows are deprived of their rights by their in-laws and parents and they have to manage their affairs themselves. Their condition worsens further when they have to look after their dependent children and when those children are thrown out of the homes with their mother. The condition of widows in rural areas is all the more serious. They are not only maltreated but are also considered ominous. They are also not permitted to take part in the family ceremonies. Being illiterate they are badly subjected to physical, mental and social exploitation.

Our country is a welfare state and, therefore, it becomes the duty of the state to rehabilitate such hapless widows and to implement welfare schemes for this purpose. But even after so many years have passed since independence, a large number of destitute women, widow and divorcee women still remain deprived of Government assistance and facilities. Most of them are unemployed and they do not get proper food. They are suffering from various diseases. It is the primary responsibility of the Government to ensure that they are provided all such opportunities and facilities so that they may live and grow in a healthy environment and are protected from all kinds of exploitation.

It is, therefore, necessary to enact a legislation for the welfare and protection of the destitute women and the widows.

Hence this Bill.

JAI PARKASH AGGARWAL

## FINANCIAL MEMORANDUM

Clause 3 of the Bill provides for the establishment of Destitute Women and Widows Welfare Authority by the Central Government. Clause 4 provides that the Destitute Women and Widows Welfare Authority shall formulate plans and prepare schemes for the welfare of the Destitute Women and Widows and that they will also register the names of all Destitute Women and Widows. Clause 5 provides that the Central Government shall provide to all the Destitute Women and the Widows financial assistance of rupees two thousand every month, free medical care and such other facilities as are necessary for their proper development and welfare. Clause 6 of the Bill provides for Central Government to provide adequate funds to the Authority for carrying out the purpose of this Act. The Bill, if enacted will therefore involve expenditure from the Consolidated Fund of the country. It is estimated that it will incur a recurring expenditure of rupees 50 crore per annum.

A non-recurring expenditure to the tune of rupees ten crore may also be involved in it.

## MEMORANDUM REGARDING DELEGATED LEGISLATION

Clause 7 of the Bill gives power to the Central Government to make rules for carrying out the purposes of this Bill. Since the rules will relate to matters of details only, the delegation of legislative power is of normal character.

## IV

## BILL NO. LXXXV OF 2006

*A Bill to provide for the freedom of earning livelihood to hawkers, vendors, rickshaw pullers and roadside mechanics and for matters connected therewith and incidental thereto.*

BE it enacted by Parliament in the Fifty-seventh Year of the Republic of India as follows:—

Short title,  
extent and  
commencement.

1. (1) This Act may be called the Hawker, Vendor, Rickshaw Puller and Roadside Mechanic (Freedom to earn livelihood) Act, 2006.

(2) It extends to the whole of India.

(3) It shall come into force on such date as the Central Government may, by notification in the Official Gazette, appoint.

Definition.

2. In this Act, unless the context otherwise requires:—

(a) “appropriate Government” means in the case of a State, The Government of the State and in all other cases, the Central Government;

(b) "hawker" means a person who sells household consumer items such as vegetables, fruits, clothes, food items, dry fruits, etc. going from house to house and street to street hawking on cart, cycle carrying basket or by any other mode;

(c) "prescribed" means prescribed by rules made under this Act;

(d) "rickshaw puller" means a person who pulls a cycle rickshaw of any kind to earn his livelihood;

(e) "roadside mechanic" includes any person who repairs cycle, cycle rickshaw, scooter, motor cycle, car and other motorized vehicles, footwears, utensils and other wares by the roadside or under a tree without any permanent structure built at the work place;

(f) "vendor" means a person who sells food items, fruits, vegetables and other small household items, from a stall or place in the open.

3. Notwithstanding anything contained in any other law for the time being in force the hawkers, rickshaw pullers, roadside mechanics, vendors, and persons carrying similar other vocations shall have complete freedom to earn their livelihood without hindrance from any authority whatsoever including those of police and local self government bodies.

Complete freedom to earn livelihood.

4. Notwithstanding anything contained in any other law for the time being in force, no authority of the local self Government such as, "municipality", Municipal Corporation, Municipal Council or by whatever name called shall impound the articles, tools, carts, cycle rickshaws, etc. belonging to the hawkers, rickshaw pullers, roadside mechanics, vendors as the case may be.

No authority to impound articles, tools, etc.

5. For earning livelihood under the provisions of this Act:—

(a) a hawker shall not hawk any article which is injurious to health and he shall not obstruct any public place and the flow of traffic;

Certain conditions to be followed by hawkers etc.

(b) a rickshaw puller and roadside mechanic shall not obstruct the flow of traffic of vehicles or pedestrians as the case may be;

(c) a vendor shall not sell anything which is injurious to health.

6. It shall be the duty of the appropriate Government to ensure strict compliance of the provisions of this Act, in a manner as may be prescribed.

Duty of appropriate Government to ensure compliance.

7. The provisions of this Act shall have effect notwithstanding anything inconsistent therewith contained in any other law for the time being in force.

Over-riding effect of the Act.

8. The Central Government may give directions to any State Government for the effective implementation of the provisions of this Act in the State.

Power to give direction.

9. If any difficulty arises in giving effect to the provisions of this Act, the Central Government may, by order published in the Official Gazette, make such provisions, not inconsistent with the provisions of this Act, as may appear to be necessary for removing the difficulty.

Power to remove difficulties.

10. The Central Government may, by notification in the Official Gazette, make rules for carrying out the purposes of this Act.

Power to make rules.

### STATEMENT OF OBJECTS AND REASONS

Our country is facing a serious problem of the constantly increasing unemployment as a result of the population explosion. Number of unemployed persons is rapidly increasing. It has become immensely difficult to get Government jobs because of the policy of to reduce staff in various government departments. The public sector undertakings are adopting voluntary retirement schemes and are being disinvested for privatisation. Agriculture, which used to provide maximum employment is also facing economic recession due to unprofitable price structure and fall in the prices of agricultural products. The Private Sector is making more and more use of computers in its work. Thus, employment is not increasing in proportion to the increasing population.

Self-employment therefore, seems to be the only solution to tackle unemployment. But, it needs money which everybody does not have. Some citizens try to earn their livelihood by pulling rickshaws or hawking or vending articles or repairing motorized vehicles, bicycles, shoes, etc. by the roadside, but most of them are intimidated by the officials of the local police or municipality. Either they have to bribe the police and or the officer of municipality or their articles and other items are taken away and confiscated. Thus, they have to live in an atmosphere of fear. They can not earn their livelihood fearlessly. Since, the Government is unable to provide employment to these poor people, they should not be deprived of the right to earn their livelihood. It is, therefore, felt that these poor people should have full freedom to earn their livelihood and they should not be interfered in any way by Police or local authorities in pursuing their profession.

Hence this Bill.

JAI PARKASH AGGARWAL

## MEMORANDUM REGARDING DELEGATED LEGISLATION

Clause 10 of the Bill gives power to the Central Government to make rules for carrying out the purposes of this Bill. The rules will relate to matters of details only. The delegation of legislative power is of normal character.

## V

## BILL NO. LXXXIX OF 2006

*A Bill to provide for compulsory emergency medical aid to the victims of accidents by private hospitals and medical practitioners and for building confidence amongst the members of the public to come forward and help the accident victims and for matters connected therewith or incidental thereto.*

BE it enacted by Parliament in the Fifty-seventh Year of the Republic of India as follows:—

1. (1) This Act may be called the Accident Victims (Compulsory Emergency Medical Aid by Private Hospitals and Medical Practitioners) Act, 2006.

Short title,  
extent and  
commencement.

(2) It extends to the whole of India.

(3) It shall come into force with immediate effect.

2. In this Act, unless the context otherwise requires,—

Definitions.

(a) "appropriate Government" means in the case of a State, the Government of that State and in all other cases, the Central Government;

102 of 1956

(b) "medical practitioner" means person holding medical qualification recognized under the Indian Medical Council Act, 1956;

(c) "medico legal case" means an accident case requiring compulsory information to the police for the purpose of taking cognizance and other formalities of registration of FIR, etc;

(d) "private hospital" includes private nursing homes and clinics being run by a medical practitioner or a group of medical practitioners or a trust or society;

(e) words and expressions used in this Act and not defined but defined in the Indian Medical Council Act, 1956 shall have the same meaning assigned to them in that Act.

Compulsory medical aid to accident victims.

3. (1) No private hospital or medical practitioner shall refuse to provide emergency medical aid to the victims of accidents on the ground that the victims have been injured in a medico legal case.

(2) The appropriate Government shall ensure that no private hospital or medical practitioner refuses to provide emergency medical aid to the victim of accidents by issuing such directions as may be necessary and prescribed.

Hospital and Medical Practitioner to conduct initial examination and stabilize the condition of the victim.

4. (1) It shall be the duty of every private hospital or medical practitioner, to conduct an initial examination of the victim and decide about the requirement of emergency treatment whenever any accident victim is taken to them.

(2) In case it is required, the private hospital or the medical practitioner shall make all necessary efforts to stabilize the condition of the victim.

(3) If the private hospital or the medical practitioner does not have the facilities for examination, and stabilizing the condition of the victim or emergency medical aid, the victim shall be immediately transferred to the nearby hospital having all these facilities.

(4) The private hospital or the medical practitioner, providing emergency treatment to the accident victim shall, in such form as may be prescribed, send to the appropriate Government, a claim for reimbursement of the expenditure incurred on the emergency medical treatment of the accident victims.

(5) The private hospital or the medical practitioner shall, within twenty-four hours of providing the emergency medical aid to the victim inform to the police station having jurisdiction of that area about the details of the accident victim.

Appropriate Government to frame scheme for reimbursement to the Private hospital or the medical practitioner.

5. The appropriate Government shall, by notification in the Official Gazette, publish a scheme for reimbursement of the expenditure incurred by any private hospital or medical practitioner in providing emergency medical aid to the accident victims.

Members of the public helping the accident victim not to be questioned unnecessarily and detained.

6. (1) The appropriate Government shall ensure that the members of the public or the medical practitioners who help the accident victim are not unnecessarily questioned or detained at police stations:

Provided that if such a person does not want to disclose his identity he shall not be compelled to do so.

(2) The appropriate Government shall ensure that the member of the public who takes the accident victim to any hospital or to any medical practitioner is paid transportation charges then and there in such manner as may be prescribed.

7. The appropriate Government shall through seminars, conferences, etc. undertake such confidence building measures as may be necessary to encourage members of the public to come forward to help the accident victims.

Appropriate Government to build confidence in members of the public.

8. The Central Government shall, after due appropriation made in this behalf, provide such sums of money as it may think fit for being utilized for the purposes of this Act.

Central Government to provide funds.

9. Whoever contravenes or attempts to contravene or abets the contravention of the provisions of this Act shall be punishable with imprisonment for a term, which may extend to three years or with fine, which may extend to five lakh rupees or with both.

Penalty.

10. Where a person committing a contravention of any of the provisions of this Act or of any rule made thereunder is a company, every person who, at the time the contravention was committed, was in charge of, and was responsible to, the company for the conduct of business of the company as well as the company, shall be guilty of the contravention and shall be liable to be proceeded against and punished accordingly:

Offence by companies.

Provided that nothing contained in this sub-section shall render any such person liable to punishment if he proves that the contravention took place without his knowledge or that he exercised all due diligence to prevent such contravention.

*Explanation.*—For the purpose of this section:—

(i) "company" means anybody corporate and include a firm or other association of individuals; and

(ii) "director", in relation to a firm, means a partner in the firm.

11. If any difficulty arises in giving effect to the provisions of this Act, the Central Government may, by order published in the Official Gazette, make such provisions not inconsistent with the provisions of this Act, as appear to it to be necessary or expedient for removing the difficulty:

Power to remove difficulties.

Provided that no such orders shall be made after the expiry of the period of three years from the date of commencement of this Act.

12. The provisions of this Act shall be in addition to, and not in derogation of the provisions in any other law, for the time being in force, relating to accident victims.

Overriding effect of the Act.

13. The Central Government may, by notification in the Official Gazette, make rules for carrying out the purposes of this Act.

Power to make rules.

## STATEMENT OF OBJECTS AND REASONS

Accidents are unfortunate and can happen with anybody at any time. But, the more unfortunate and sad part of it is the indifferent attitude of the people and medical practitioners towards the accident victims. Ironically, accident site attracts instant crowd but the victim who needs immediate attention is ignored due to fear of getting entangled in police case. Even if a fortunate victim is picked up by some good samaritan, he is stuck up at the private hospital or the medical practitioner who refuses to provide emergency medical aid stating it to be a medico legal case. As a result of this refusal by hospital and medical practitioner, the precious time available with them to save the life of the victim is lost leading to loss of life of the individual. In a civilized society, such an act by these hospitals and doctors goes against the ethics of their profession besides being against the morality. It becomes the duty of a person in the medical profession to save a precious life without going into the legality of the accident. The people and the medical professionals do not come forward to help the victim mainly due to fear of harassment. At time, it has also been seen that private hospitals and medical practitioners refuse to provide treatment as the victims are not in a position to make payment for immediate medical care or have no medical insurance which would entitle them to reimbursement.

Besides being victims of accidents at construction site or in public violence, these victims mainly belong to road accidents. According to the World Report on Road Traffic Injury Prevention released by WHO in 2004, 12 lakh people die each year in road accidents. The report highlighted that while in high income countries, there is reasonably well organized ambulance based rescue system, in middle and low income countries, assistance of bystander is most common (which is devoid of in our country). Further, it is a proven fact that a number of accident victims can be saved if they receive immediate medical attention.

In *Pt. Parmanand Katara vs Union of India* AIR 1989, the Hon'ble Supreme Court had observed as under.

"Every injured citizen brought for medical treatment should instantaneously be given medical aid to preserve life and thereafter the procedural criminal law should be allowed to operate in order to avoid negligent death. There is no legal impediment for a medical professional when he is called upon and requested to attend to an injured person needing his medical assistance immediately. The effort to save the person should be a top priority not only of the medical professional but of the police and other citizens. There are no provisions in the Indian Penal Code/Code of Criminal Procedure/Motor Vehicles Act which prevents doctors from promptly attending to seriously injured persons and accident cases before the arrival of the police and taking into cognizance of such cases, preparation of FIR and other formalities by Police."

Following the Supreme Court Judgement in 1989, the Motor Vehicles Act was amended in 1994 and under section 134, it was made mandatory for the driver and the owner of the vehicle to take the accident victim to the nearest doctor and for the doctor to treat the victim without waiting for any formality. But, even after all this, the situation has not improved.

In addition to this, in view of the dubious distinction of maximum road accident in our country, there is an urgent need for confidence building amongst the public and the medical practitioners so that they come forward and help the accident victims in time to save their lives. In many countries, there are laws making it compulsory for hospitals and medical practitioners to provide treatment to accident victims and these laws provided for punishment if they refuse to do so.

In view of the above, legislation on this subject is long overdue.

Hence this Bill.

MAHENDRA MOHAN



### FINANCIAL MEMORANDUM

Clause 5, of the Bill provides that the appropriate Government shall frame scheme for reimbursement of the expenditure incurred by the private hospital or the medical practitioner in providing emergency medical aid to the accident victims. Clause 6 provides that appropriate Government shall ensure that the member of the public who takes the accident victim to the hospital or to the medical practitioner will be paid transportation charges. The expenditure on this account for Union Territories shall be borne by the Central Government. Further, Clause 8 provides that the Central Government shall make the funds available for being utilized for the purpose of this Act. The Bill, if enacted, will involve expenditure from the Consolidated Fund of India to the tune of rupees twenty crore per annum.

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### MEMORANDUM REGARDING DELEGATED LEGISLATION

Clause 13 of the Bill empowers the Central Government to make rules for carrying out the purposes of the Bill. As the matter will relate to details only, the delegation of legislative powers is of normal character.

## VI

## BILL NO. LXXXVIII OF 2006

*A Bill to provide for regulation of increasing clinical trials of various new drugs on patients being conducted by various pharmaceutical companies in the country to verify their clinical pharmacology or adverse effects; to determine their safety and efficacy and to protect the interests of patients undergoing these trials in the absence of any information or contract by these companies and for matters connected therewith or incidental thereto.*

BE it enacted by Parliament in the Fifty-seventh Year of the Republic of India as follows:—

Short title,  
extent and  
commencement.

1. (1) This Act may be called the Clinical Trial of Drugs on Patients (Regulation) Act, 2006.

(2) It shall come into force with immediate effect.

Definitions.

2. In this Act, unless the context otherwise requires,—

(a) "clinical trial" means the process of verifying the efficacy, safety and adverse effect of any new drug by pharmaceutical companies by testing it clinically on any patient with or without his consent;

(b) "fund" means Clinical Trial Fund created under section 7;

(c) "pharmaceutical company" means any establishment contracting or outsourcing clinical trials of any drug on patients;

(d) "prescribed" means prescribed by rules made under this Act; and

(e) "Registry" means Clinical Trial of Drugs Registry established under section 4.

3. No pharmaceutical company shall conduct or outsource any clinical trial of a drug on any patient unless such clinical trial is registered under the provisions of this Act.

Pharmaceutical companies not to undertake clinical trial without registration.

4. (1) The Central Government shall, by notification in the Official Gazette, establish a Registry to be known as the Clinical Trial of Drugs Registry for the purposes of performing functions assigned under this Act.

Establishment of Clinical Trial of Drugs Registry.

(2) The Registry shall be headed by a Registrar and shall have such number of officers and employees as may be specified and provided to it by the Central Government.

(3) The headquarters of the Registry shall be at Lucknow.

(4) The terms and conditions of service of the Registrar, officers and employees of the Registry shall be such as may be prescribed.

5. (1) Every pharmaceutical company willing to conduct clinical trial of any drug in the country shall make an application for the registration of clinical trial to the Registry in such form and in such manner as may be prescribed:

Registration of clinical trials.

Provided that the pharmaceutical companies which are conducting clinical trials in the country shall apply for registration of the clinical trial with the Registry within one month of the commencement of this Act.

(2) The Registry shall, within one month of the filing of the application under sub-section (1), either register the trial after verifying the fulfilment of the requirements under the provisions of this Act or reject the application.

(3) While rejecting any application for clinical trial under sub-section (2), the Registry shall give the reasons in writing to the concerned pharmaceutical company.

6. (1) Every pharmaceutical company or hospital or medical practitioner before conducting clinical trial shall explain the whole process to the patient and obtain his consent in writing.

Patient to be paid and explained the process of clinical trial.

(2) Every patient undergoing clinical trial shall be paid fifty thousand rupees by the pharmaceutical company conducting or outsourcing the trial of drugs before starting the trial.

(3) The hospital conducting the clinical trial shall ensure that the trial is conducted by the trained and qualified persons and ensure for its proper monitoring.

7. (1) The Central Government, shall by notification in the Official Gazette, constitute a Clinical Trial Fund for the welfare of the family of the person and the person himself in case the trial goes wrong.

Clinical Trial Fund.

(2) The fund shall consist of such sums of money as may be contributed in it by the Central and the State Governments and the donations received from various voluntary organizations and individuals.

(3) The Central Government shall administer the fund in such manner as may be prescribed.

Hospital to record and find reasons if trial goes wrong.

8. In case the trial goes wrong, it shall be the responsibility of the hospital conducting the clinical trial to record and find out the reasons and fix the responsibility:

Provided that if the trial goes wrong due to negligence, the patient or his immediate family shall be entitled to claim damages from the Hospital or Pharmaceutical Company, as the case may be.

Central Government to provide funds.

9. The Central Government shall, after due appropriation made in this behalf, provide such sums of money as it may think fit for being utilized for the purposes of this Act.

Penalty

10. Whoever contravenes or attempts to contravene or abets the contravention of the provisions of this Act shall be punishable with imprisonment for a term, which may extend to three years or with fine, which may extend to twenty lakhs rupees or with both.

Offences by companies

11. Where a person committing a contravention of any of the provisions of this Act or of any rule made thereunder is a company, every person who, at the time the contravention was committed, was in charge of, and was responsible to, the company for the conduct of business of the company as well as the company, shall be guilty of the contravention and shall be liable to be proceeded against and punished accordingly:

Provided that nothing contained in this sub-section shall render any such person liable to punishment if he proves that the contravention took place without his knowledge or that he exercised all due diligence to prevent such contravention.

*Explanation.*— For the purpose of this section:—

(i) "Company" means any body Corporate and include a firm or other association of individuals; and

(ii) "director", in relation to a firm, means a partner in the firm.

Power to remove difficulties.

12. If any difficulty arises in giving effect to the provisions of this Act, the Central Government may, by order published in the Official Gazette, make such provisions, not inconsistent with the provisions of this Act, as appear to it to be necessary or expedient for removing the difficult:

Provided that no such order shall be made after the expiry of the period of three years from the date of commencement of this Act.

Overriding effect

13. The provisions of this Act shall be in addition to, and not in derogation of, the provisions in any other law, for the time being in force, relating to clinical trial of drugs.

Power to make rules.

14. The Central Government may, by notification in the official Gazette, make rules for carrying out the purposes of this Act.

## STATEMENT OF OBJECTS AND REASONS

In the near future, India is going to be the world's favourite destination for conducting clinical trials of various new drugs being manufactured by pharmaceutical giants in the world. These major pharmaceutical companies are outsourcing the clinical trials in our country in a big way. According to a study, the total market for clinical research activities in India is expected to touch rupees two thousand crores. It has been further stated in the study that in the next two years thirty per cent of global clinical trials will take place outside the US and western Europe and India would be the most favoured country. With the cut-throat competition, pharmaceutical companies are facing a lot of financial crunch due to spiraling Research and Development cost, and increasing overheads, therefore, outsourcing of clinical trial appears to be the viable option for them. By contracting such work to India, these companies can save from forty to sixty per cent of the cost. Last year, nearly 175 trials were conducted in the country. These trials are not limited to multinational companies but also to Indian pharma companies which are also contracting trial for research purposes in view of the new patent regime. There is no doubt that if India has to participate in new drug development then clinical trials are essential because the general use of drugs have to be tested in a variety of ethnic groups or different genetic or race profiles. Though our country can take advantage of this situation but at the same time, there are concerns which show that the Indians are being used as guinea pigs for these clinical trials. Leading medical journals have noted how developing countries with poor and illiterate patients, weak legal framework, lax bureaucracy and financially crunched hospitals have become hunting grounds for pharma giants to test new drugs. The lucrative offers for trials are difficult to resist as they give plenty of money and promises.

In the recent past, over 430 unsuspecting young women were used as guinea pigs by researchers to test if anti-cancer drug Letrozole could be used to increase ovulation. According to a report published in Monthly Index of Medical Specialities in December, 2003, Letrozole belongs to Schedule G of the Drugs and Cosmetics Rules and can be sold only against prescription. But it was found out that many unauthorized practitioners had been prescribing and retailers selling the drug. In another case, new chemical entities discovered in the US were unlawfully tested on 26 oral cancer patients at the Regional Cancer Centre in Thiruvananthapuram. Fairplay requires the patient undergoing clinical trial should be explained the whole process of the trial and his consent may be obtained in writing. But, with the kind of money involved in these trials nobody bothers about these things. Further, in case the trial goes wrong, there is no legal remedy available in our country and the law is silent about any compensation to be paid to the patient on whom the trial was conducted. In US and UK, the patients on whom the trials are conducted are paid anywhere between two to three lakhs by the pharmaceutical companies. But, in India, the poor illiterate patients are not paid a single paisa and rather are obliged by the doctor informing them that they are being treated by an imported drug free of charge which they cannot afford.

It is also required in these cases that the trained persons should undertake the job of clinical trial which should be closely supervised and monitored and responsibility should also be fixed if the trial goes wrong. In view of the fact that extreme poverty and illiteracy make us susceptible to such trials and the law provides no assistance to the patients in conducting of clinical trials by pharma companies in our country, there is an urgent need for regulation on this aspect covering the various aforesaid propositions.

Hence this Bill.

MAHENDRA MOHAN

## FINANCIAL MEMORANDUM

Clause 4 of the Bill provides the establishment of the Clinical Trial of Drugs Registry, clause 7 of the Bill provides that the Central Government shall contribute money to Clinical Trial Fund. Further, clause 9 provides that Central Government shall provide funds for being utilized for the purpose of this Act. The Bill, if enacted, involve expenditure from the consolidated fund of India to the tune of rupees twenty crore per annum. No non-recurring expenditure is likely to be involved.

## MEMORANDUM REGARDING DELEGATED LEGISLATION

Clause 14 of the Bill empowers the Central Government to make rules for carrying out the purposes of the Bill. As the matter will relate to details only, the delegation of powers is of normal character.

YOGENDRA NARAIN,  
*Secretary-General.*